

Package leaflet: Information for the patient

Celecoxib 100 mg capsules, hard
Celecoxib 200 mg capsules, hard
celecoxib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Celecoxib is and what it is used for
2. What you need to know before you take Celecoxib
3. How to take Celecoxib
4. Possible side effects
5. How to store Celecoxib
6. Contents of the pack and other information

1. What Celecoxib is and what it is used for

Celecoxib is used in adults for the relief of signs and symptoms of **rheumatoid arthritis**, **osteoarthritis** and **ankylosing spondylitis**.

Celecoxib belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), and specifically a sub-group known as COX-2 inhibitors. Your body makes prostaglandins that may cause pain and inflammation. In conditions such as rheumatoid arthritis and osteoarthritis your body makes more of these. Celecoxib acts by reducing the production of prostaglandins, thereby reducing the pain and inflammation.

Celecoxib is indicated in adults.

2. What you need to know before you take Celecoxib

Do not take Celecoxib:

- if you are allergic to celecoxib or any of the other ingredients of this medicine (listed in section 6)
- if you have had an allergic reaction to a group of medicines called “sulfonamides” like some antibiotics used to treat infections, or some water tablets/diuretics
- if you **currently** have an ulcer in your stomach or intestines, or bleeding in your stomach or intestines
- if as a result of taking acetylsalicylic acid (aspirin) or any other anti-inflammatory and pain-relieving medicine (NSAID) you have had asthma, nose polyps, severe nose congestion or runny nose, or an allergic reaction such as an itchy skin rash, swelling of the face, lips, tongue or throat, breathing difficulties or wheezing
- if you are pregnant. If you can become pregnant during ongoing treatment you should discuss methods of contraception with your doctor

- if you are breast-feeding
- if you have severe liver disease
- if you have severe kidney disease
- if you have an inflammatory disease of the intestines such as ulcerative colitis or Crohn's disease
- if you have heart failure, established ischaemic heart disease, or cerebrovascular disease, e.g. you have been diagnosed with a heart attack, stroke, or transient ischaemic attack (temporary reduction of blood flow to the brain; also known as "mini-stroke"), angina, or blockages of blood vessels to the heart or brain
- if you have or have had problems with your blood circulation (peripheral arterial disease) or if you have had surgery on the arteries of your legs.

Warnings and precautions

Talk to your doctor or pharmacist before taking Celecoxib:

- if you have **previously** had an ulcer or bleeding in your stomach or intestines
- **(Do not take Celecoxib** if you **currently** have an ulcer or bleeding in your stomach or intestine)
- if you are taking acetylsalicylic acid (aspirin; even at low dose for heart protective purposes)
- if you use medicines to reduce blood clotting (e.g. warfarin or warfarin-like medicines e.g. apixaban, dabigatran, rivaroxaban)
- if you are using medicines called corticosteroids (e.g. prednisone) used to treat inflammation
- if you are using Celecoxib at the same time as other non-acetylsalicylic NSAIDs such as ibuprofen or diclofenac. The use of these medicines together should be avoided
- if you smoke, have diabetes, raised blood pressure or raised cholesterol
- if your heart, liver or kidneys are not working well your doctor may want to keep a regular check on you
- if you have fluid retention (such as swollen ankles and feet)
- if you are dehydrated, for instance due to sickness, diarrhoea or the use of diuretics (used to treat excess fluid in the body)
- if you have had a serious allergic reaction or a serious skin reaction to any medicines
- if you feel ill due to an infection or think you have an infection, as Celecoxib may mask a fever or other signs of infection and inflammation
- if you are over 65 years of age your doctor may want to keep a regular check on you

During treatment

As with other NSAIDs (e.g. ibuprofen or diclofenac) this medicine may lead to an increase in blood pressure, and so your doctor may ask to monitor your blood pressure on a regular basis.

Some cases of severe liver reactions, including severe liver inflammation, liver damage, liver failure (some with fatal outcome or requiring liver transplant), have been reported with celecoxib. Of the cases that reported time to onset, most severe liver reactions occurred within one month of start of treatment (see Possible side effects).

Celecoxib may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems to become pregnant (see section on Pregnancy and breast-feeding).

Children and adolescents

Celecoxib is for adults only, it is not for use in children and adolescents.

Other medicines and Celecoxib

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- Dextromethorphan (used to treat coughs)
- ACE inhibitors, angiotensin II antagonists and beta blockers (used for high blood pressure and heart failure)
- Diuretics (used to treat excess fluid in the body)
- Fluconazole and rifampicin (used to treat fungal and bacterial infections)
- Warfarin or other oral anticoagulants (“blood-thinning” agents that reduce blood clotting)
- Lithium (used to treat some types of depression)
- Other medicines to treat depression, sleep disorders, high blood pressure or an irregular heartbeat
- Neuroleptics (used to treat some mental health conditions)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis and leukaemia)
- Carbamazepine (used to treat epilepsy/seizures and some forms of pain or depression)
- Barbiturates (used to treat epilepsy/seizures and some sleep disorders)
- Cyclosporin and tacrolimus (used for immune system suppression e.g. after transplants)

Celecoxib can be taken with low dose acetylsalicylic acid (aspirin; 75 mg or less daily). Ask your doctor for advice before taking both medicines together.

Celecoxib with alcohol

It is not recommended to consume alcohol with this medicine because the consumption of alcohol and NSAIDs may increase the risk of gastrointestinal problems.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Celecoxib if you are pregnant or can become pregnant (i.e. if you are of child bearing potential and not using adequate contraception) during ongoing treatment. If you become pregnant during treatment with Celecoxib you should discontinue the treatment and contact your doctor for alternative treatment.

Breast-feeding

Do not take Celecoxib during breast-feeding.

Fertility

NSAIDs, including Celecoxib, may make it more difficult to become pregnant. You should tell your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Driving and using machines

You should be aware of how you react to Celecoxib before you drive or operate machinery. If you feel dizzy or drowsy after taking Celecoxib, do not drive or operate machinery until these effects wear off.

Celecoxib contains lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Celecoxib

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you think or feel that the effect of Celecoxib is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will tell you what dose you should take. As the risk of side effects associated with heart problems may increase with dose and duration of use, it is important that you use the lowest dose that controls your pain and you should not take Celecoxib for longer than necessary to control symptoms.

Contact your doctor within two weeks of starting treatment if you do not experience any benefit.

The recommended dose is:

For osteoarthritis the recommended dose is 200 mg each day taken:

- one 200 mg capsule once a day or
- one 100 mg capsule twice a day.

In some circumstances, your doctor may increase your dose to a maximum of 400 mg, if needed. This should be taken as 200 mg twice a day.

For rheumatoid arthritis the recommended dose is 200 mg each day, taken:

- one 100 mg capsule twice a day.

In some circumstances, your doctor may increase your dose to a maximum of 400 mg, if needed. This should be taken as 200 mg twice a day.

Celecoxib 200 mg:

- The dose of 200 mg (taken as one 100 mg capsule twice a day) cannot be achieved with Celecoxib 200 mg capsules, hard. Please consult your doctor.

For ankylosing spondylitis the recommended dose is 200 mg each day taken:

- one 200 mg capsule once a day or
- one 100 mg capsule twice a day.

In some circumstances, your doctor may increase your dose to a maximum of 400 mg, if needed. This should be taken as 400 mg once a day or 200 mg twice a day.

Mild to moderate kidney or liver problems: make sure your doctor knows if you have liver or kidney problems as you may need a lower dose.

The elderly, especially those with a weight less than 50 kg: if you are over 65 years of age and especially if you weigh less than 50 kg, your doctor may want to monitor you more closely.

You should not take more than 400 mg per day.

Use in children and adolescents

Celecoxib is for adults only, it is not for use in children.

Method of administration

Celecoxib is for oral use. Celecoxib should be swallowed whole with a drink of water. The capsules can be taken at any time of the day, with or without food. However, try to take each dose of Celecoxib at the same time each day.

If you take more Celecoxib than you should

You should not take more capsules than your doctor tells you to. If you take too many capsules contact your doctor, pharmacist or hospital and take your medicine with you.

If you forget to take Celecoxib

If you forget to take a capsule, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

If you stop taking Celecoxib

Suddenly stopping your treatment with Celecoxib may lead to your symptoms getting worse.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects listed below were observed in arthritis patients who took Celecoxib. Side effects marked with an asterisk (*) are listed below at the higher frequencies that occurred in patients who took Celecoxib to prevent colon polyps. Patients in these studies took Celecoxib at high doses and for a long duration.

If any of the following happen, stop taking Celecoxib and tell your doctor immediately:

If you have:

- a serious allergic reaction (including potentially fatal anaphylactic shock) such as skin rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or difficulty breathing or swallowing
- a delayed allergic reaction with possible symptoms such as rash, swelling of the face, fever, swollen glands, and abnormal test results (e.g. liver, blood cell (eosinophilia, a type of raised white blood cell count)
- a serious skin reaction such as Stevens-Johnson syndrome with severe blistering and bleeding in the lips, eyes, mouth, nose and genitals and toxic epidermal necrolysis which can cause rash, blistering or peeling of the skin, or a serious skin infection
- a heart attack*, pain in the chest (generalised pain not related to the heart) which may spread to the neck and shoulders
- heart failure (disease of the heart with shortness of breath, and swelling of the feet or legs due to fluid build-up)
- meningitis (infection around the brain or spinal cord)
- a stroke* (damage to part of the brain caused by an interruption to its blood supply)
- bleeding within the brain causing death
- deep vein thrombosis (blood clot usually in the leg, which may cause pain, swelling or redness of the calf or breathing problems)
- a blockage of an artery or vein in the eye leading to partial or complete loss of vision
- a blockage of the lung artery. Symptoms may include sudden breathlessness, sharp pains when you breathe or collapse
- pneumonitis, pneumonia (chest infection (possible cough, fever, wheezing, difficulty breathing))
- worsening of epilepsy (possible more frequent and/or severe seizures)
- severe stomach pain or any sign of bleeding in the stomach or intestines, such as passing black or bloodstained stools, or vomiting blood, inflammation of the intestine or colon
- ulcers in the stomach, gullet or intestines or rupture of the intestine (can cause stomach ache, fever, nausea, vomiting, intestinal blockage)
- an inflammation of the pancreas (can lead to stomach pain)

- liver failure, liver damage and severe liver inflammation (sometimes fatal or requiring liver transplant). (Symptoms may include nausea (feeling sick), diarrhoea, jaundice (your skin or the whites of your eyes look yellow), dark urine, pale stools, bleeding easily, itching or chills)
- other liver problems (such as a blockage in the bile duct, which may be accompanied by symptoms such as discoloured stools, nausea and yellowing of the skin or eyes)
- a reduction in the number of red and white blood cells and platelets (may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections)
- Inflammation of the kidneys and other kidney problems (such as nephrotic syndrome, possible kidney failure), you may notice little or no urine being produced, cloudy urine, blood in the urine, foamy urine, fatigue and a loss of appetite
- kidney stones (which may lead to stomach or back pain, blood in urine).

Other side effects

Very common: may affect more than 1 in 10 people:

- High blood pressure, including worsening of existing high blood pressure*.

Common: may affect up to 1 in 10 people:

- Fluid build-up with swollen ankles, legs and/or hands
- Urinary infection
- Shortness of breath*, sinusitis (sinus inflammation, sinus infection, blocked or painful sinuses), blocked or runny nose, sore throat, cough, colds, flu-like symptoms
- Dizziness, difficulty sleeping
- Vomiting*, stomach ache, diarrhoea, indigestion, wind
- Rash, itching
- Muscle stiffness
- Difficulty swallowing*
- Headache
- Nausea (feeling sick)
- Painful joints
- Worsening of existing allergies
- Accidental injury.

Uncommon: may affect up to 1 in 100 people:

- Palpitations (awareness of heart beat), fast heart rate
- Abnormalities in liver-related blood tests
- Abnormalities in kidney-related blood tests
- Anaemia (changes in red blood cells that can cause fatigue and breathlessness)
- Anxiety, depression, tiredness, drowsiness, tingling sensations (pins and needles)
- High levels of potassium in blood test results (can cause nausea (feeling sick), fatigue, muscle weakness or palpitations)
- Impaired or blurred vision, ringing in the ear, mouth pain and sores, difficulty hearing*
- Constipation, burping, stomach inflammation (indigestion, stomach ache or vomiting), worsening of inflammation of the stomach or intestine
- Leg cramps
- Raised itchy rash (hives), skin discolouration (bruising)
- Eye (conjunctiva) inflammation
- Difficulty breathing
- Chest pain (generalised pain not related to the heart).

Rare: may affect up to 1 in 1,000 people:

- Inflammation of the gullet (oesophagus)
- Low levels of sodium in the blood (a condition known as hyponatraemia)

- Difficulty coordinating muscular movements
- Feeling confused, hallucinations, changes in the way things taste
- Increased sensitivity to light
- Loss of hair
- Bleeding in the eye
- Irregular heartbeat
- Flushing
- Inflammation of the bowel which can cause diarrhoea, usually with blood and mucus, stomach pain and fever or worsening of the inflammation
- Menstrual disturbances.

Very rare: may affect up to 1 in 10,000 people:

- Exfoliative dermatitis and acute generalised exanthematous pustulosis (symptoms include the skin becoming red with swollen areas covered in numerous small pustules)
- Inflamed blood vessels (can cause fever, aches, purple blotches on the skin)
- Muscle pain and weakness
- Impaired sense of smell.

Not known: frequency cannot be estimated from the available data

- Decreased fertility in females, which is usually reversible on discontinuation of the medicine.

In clinical studies not associated with Arthritis or other arthritic conditions, where Celecoxib was taken at doses of 400 mg per day for up to 3 years, the following additional side effects have been observed:

Common: may affect up to 1 in 10 people:

- Stomach problems: irritable bowel syndrome (can include stomach ache, diarrhoea, indigestion, wind)
- Difficulty passing urine, increases in the level of creatinine which would be seen in blood test, increase in the prostate size in men which can lead to a more frequent need to pass urine or urine retention
- Weight gain.

Uncommon: may affect up to 1 in 100 people:

- Stomach problems: stomach infection (which can cause irritation and ulcers of the stomach and intestines)
- Lower limb fracture
- Shingles, eczema (dry itchy rash)
- Floaters in the eye causing blurred or impaired vision, vertigo due to inner ear troubles, sore, inflamed or bleeding gums, mouth sores
- Excessive urination at night, bleeding from piles/ haemorrhoids, frequent bowel movements
- Fatty lumps in skin or elsewhere, ganglion cyst (harmless swellings on or around joints and tendons in the hand or foot), difficulty speaking, abnormal or very heavy bleeding from the vagina, breast pain
- High levels of sodium in blood test results.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail:

medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Celecoxib

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister/bottle after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Celecoxib contains

- The active substance is celecoxib.
- Each hard capsule contains 100 mg celecoxib.
- Each hard capsule contains 200 mg celecoxib.
- The other ingredients are: sodium laurilsulfate, povidone K29-32, lactose monohydrate, croscarmellose sodium, magnesium stearate, silica colloidal anhydrous.
- Capsules shell contain:
 - titanium dioxide (E171), gelatin, indigo carmine (E132)
 - titanium dioxide (E171), gelatin, black iron oxide (E172) red iron oxide (E172), yellow iron oxide (E172).
- Ink contains shellac, black iron oxide (E172), propylene glycol.

What Celecoxib looks like and contents of the pack

Celecoxib is available as hard capsules.

Celecoxib 100 mg: blue opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is printed with MYLAN over CE 100 in black ink around the cap and body.

Celecoxib 200 mg: light brown opaque cap and white opaque body, hard-shell gelatin capsule filled with white to off-white powder. The capsule is printed with MYLAN over CE 200 in black ink around the cap and body.

Celecoxib 100 mg is available in blisters of 10, 20, 30, 40, 50, 60, 100, 1x30, 1x60 unit dose blisters, or in bottles of 500.

Celecoxib 200 mg is available in blisters of 10, 20, 30, 50, 60, 100, 1 x 30, 1 x 60 unit dose blisters, or in bottles of 500.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Generics [UK] Ltd,

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This medicinal product is authorised in the Member States of the EEA under the following names:

Member State	Name of medicinal product
Belgium	Celecoxib Mylan 100 mg capsule, hard
	Celecoxib Mylan 200 mg capsule, hard
Czech Republic	Celecoxib Mylan 100 mg
	Celecoxib Mylan 200 mg
France	CELECOXIB MYLAN 100 mg, gélule
	CELECOXIB MYLAN 200 mg, gélule
Germany	Celecoxib Mylan 100 mg Hartkapseln
	Celecoxib Mylan 200 mg Hartkapseln
Ireland	Celecoxib 100 mg Capsules, hard
	Celecoxib 200 mg Capsules, hard
Italy	Celecoxib Mylan
Luxembourg	Celecoxib Mylan 100 mg gélule
	Celecoxib Mylan 200 mg gélule
Portugal	Sedrivalex
Spain	Celecoxib MYLAN 100 mg cápsulas duras
	Celecoxib MYLAN 200 mg cápsulas duras
The Netherlands	Celecoxib Mylan 100 mg, capsules, hard
	Celecoxib Mylan 200 mg, capsules, hard
United Kingdom	Celecoxib 100 mg Capsules, hard
	Celecoxib 200 mg Capsules, hard

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